

REMARKS

Applicants gratefully acknowledge the Examiner's indication of allowable subject matter in the present application. In accordance with the Examiner's suggestions, claim 22 has been amended.

Applicant requests consideration of claims 41-50. As discussed with the Examiner via telephone, Applicant presented claims 41-50 in a Preliminary Amendment filed with the U.S. Patent and Trademark Office on September 7, 2004, i.e., before the issuance of the Office Action dated November 16, 2004. A supplemental copy of the Preliminary Amendment is attached. The Examiner represented during the telephone conference that the next Office Action will not be made final because claims 41-50 were presented earlier but not considered in the Office Action dated November 16, 2004.

A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier. Claims 1-50 are pending in this application.

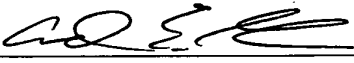
Applicant believes that the present application is in condition for allowance. The Examiner is invited to contact the undersigned by telephone if it is believed that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of

papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R.
§1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date February 15, 2005

By 

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5349
Facsimile: (202) 672-5399

Andrew E. Rawlins
Attorney for Applicant
Registration No. 34,702

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: José Rafael GARZA ALVAREZ
 Title: INTRAGASTRIC BALLOON ASSEMBLY
 Appl. No.: 10/656,219
 Filing Date: 09/08/2003
 Examiner: Unassigned
 Art Unit: 3736

**AMENDMENT TRANSMITTAL**

Mail Stop Amendment
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

Sir:

Transmitted herewith is an amendment in the above-identified application.

- ☒ [X] Small Entity status under 37 C.F.R. § 1.9 and § 1.27 has been established by a previous assertion of Small Entity status.
- ☐ [] Assertion of Small Entity status is enclosed.
- ☒ [X] The fee required for additional claims is calculated below:

	Claims As Amended		Previously Paid For		Extra Claims Present		Rate		Additional Claims Fee
Total Claims:	50	-	40	=	10	x	\$18.00	=	\$180.00
Independent Claims:	4	-	3	=	1	x	\$86.00	=	\$86.00
First presentation of any Multiple Dependent Claims:						+	\$290.00	=	\$0.00
CLAIMS FEE TOTAL									= \$266.00

- ☐ [] Applicant hereby petitions for an extension of time under 37 C.F.R. § 1.136(a) for the total number of months checked below:

<input type="checkbox"/>	Extension for response filed within the first month:	\$110.00	\$0.00
<input type="checkbox"/>	Extension for response filed within the second month:	\$420.00	\$0.00
<input type="checkbox"/>	Extension for response filed within the third month:	\$950.00	\$0.00
<input type="checkbox"/>	Extension for response filed within the fourth month:	\$1,480.00	\$0.00
<input type="checkbox"/>	Extension for response filed within the fifth month:	\$2,010.00	\$0.00
	EXTENSION FEE TOTAL:		\$0.00
<input type="checkbox"/>	Statutory Disclaimer Fee under 37 C.F.R. 1.20(d):	\$110.00	\$0.00
	CLAIMS, EXTENSION AND DISCLAIMER FEE TOTAL:		\$266.00
<input checked="" type="checkbox"/>	Small Entity Fees Apply (subtract ½ of above):		\$133.00
	TOTAL FEE:		\$133.00

- ☐ Please charge Deposit Account No. 19-0741 in the amount of \$133.00. A duplicate copy of this transmittal is enclosed.
- ☒ A check in the amount of \$133.00 is enclosed.
- ☒ The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Please direct all correspondence to the undersigned attorney or agent at the address indicated below.

Respectfully submitted,

Date 9/7/04

FOLEY & LARDNER LLP
 Customer Number: 22428
 Telephone: (202) 672-5300
 Facsimile: (202) 672-5399

By Joann K. Corey

Joann K. Corey
 Attorney for Applicant
 Registration No. 52,769



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Title: INTRAGASTRIC BALLOON ASSEMBLY
Inventor(s): José Rafael GARZA ALVAREZ Dkt. No. 029856-0102
Appl. No.: 10/656,219 AERA/JKC

- Preliminary Amendment (13 pgs.);
- Amendment Transmittal (2 pgs.); and
- Check Number 38214 for \$133.00.

Due Date: N/A

Date Filed: SEP 07 2004

Insp. By: 10MP



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: José Rafael GARZA ALVAREZ
Title: INTRAGASTRIC BALLOON ASSEMBLY
Appl. No.: 10/656,219
Filing Date: 09/08/2003
Examiner: Unassigned
Art Unit: 3736



PRELIMINARY AMENDMENT UNDER 37 C.F.R. § 1.115

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Prior to examination of the present Continuing Application, Applicant respectfully requests that the application be amended as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this document.

Remarks/Arguments begin on page 13 of this document.

Please amend the application as follows:

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

1. (Original) An intragastric balloon assembly for reducing the food intake of a person suffering from obesity, the intragastric balloon assembly comprising:

a balloon made of an acid resistant distensible material;

an inflating catheter joined at one end to the balloon and configured to inflate the balloon;

a rigid support including an elongated element formed unitarily with the balloon and having a diameter that is larger at an end joined to the balloon and becomes smaller towards an opposing end, said rigid support being configured for use as a guideline and tractor to introduce the balloon into a stomach through a mouth and as a support to maintain the balloon in a substantially fixed position, said rigid support having a groove along a length of the rigid support from the end joined to the balloon and extending up to approximately 15 cm from the end joined to the balloon;

a handle disposed at the opposing end of the rigid support and formed unitarily with the rigid support to permit said rigid support to be held during surgery;

said inflating catheter being fixedly joined at one end to the balloon proximate the rigid support and housed along at least a portion of the length of the inflating catheter within the groove of the rigid support, and configured to be carried along with the rigid support when the assembly is introduced into the stomach and to be detachable from the rigid support for fixation;

an inflating valve configured to at least one of inflate and deflate the balloon that is joined to the inflating catheter and that has at least two flanges for fixation; and

a fixing plate having a first hole with a circular flange formed therein which is configured to adjust and fix the rigid support, a second hole that receives the inflating catheter, and a plurality of fixation holes configured to join the plate by at least one of suture stitches and staples to abdominal tissue.

2. (Original) An intragastric balloon assembly according to claim 1, wherein the capacity of the balloon is about 200 to 1000 c.c.
3. (Original) An intragastric balloon assembly according to claim 1, wherein the balloon has a substantially circular shape.
4. (Original) An intragastric balloon assembly according to claim 1, wherein the balloon has a substantially bilobate shape.
5. (Original) An intragastric balloon assembly according to claim 1, wherein the balloon has a substantially kidney shape.
6. (Original) An intragastric balloon assembly according to claim 1, wherein the rigid support is made of silicone.
7. (Original) An intragastric balloon assembly according to claim 1, wherein the inflating catheter has diameter of about 1.5 to 2.0 mm and a length of approximately 20 cm.
8. (Original) An intragastric balloon assembly according to claim 1, wherein the fixing plate has a thickness of approximately 1.5 mm, and is made of at least one of silicone and inert plastic of higher hardness.
9. (Original) An intragastric balloon assembly according to claim 1, wherein the fixing plate has a shape selected from circular, ovoid and squared.
10. (Original) An intragastric balloon assembly according to claim 1, wherein the fixing plate and inflating valve are disposed in a single integrated plate.
11. (Original) An intragastric balloon assembly according to claim 10, wherein the integrated fixing plate has the circular flange and the inflating valve contiguously disposed thereon, so that the inflating catheter can be fixed by an inferior side of the fixing

plate to the inflating valve and the rigid support can be passed through the hole and fixed to the circular flange.

12. (Original) An intragastric balloon assembly according to claim 10, wherein the integrated fixing plate has the inflating valve, the first hole, and a tubular element disposed at the center of the inflating valve, so that the rigid support can be passed through said tubular element; and the flange on an upper side of the inflating valve to suture and fix the rigid support under tension

13. (Original) An intragastric balloon assembly according to claim 1, wherein the rigid support and the balloon are partially covered by a layer of a material configured to promote fibrosis and cicatrisation in regions that will contact tissues.

14. (Original) An intragastric balloon assembly according to claim 13, wherein the fibrosis and cicatrisation promoting material is selected from goretex and mersilene.

15. (Original) An intragastric balloon assembly according to claim 1, further comprising a circular reinforcement disposed adjacent to a base of the balloon where the rigid support emerges, integrally formed with the balloon and having a plurality of embossments formed thereon radially distributed on an edge thereof, said circular reinforcement being configured to be adhered to an inner wall of the stomach, when setting the balloon assembly in place, to seal a hole formed therein.

16. (Original) An intragastric balloon assembly according to claim 15, wherein the circular reinforcement is made of the same material as the balloon.

17. (Original) An intragastric balloon assembly according to claim 15, further comprising a foldable plastic screen disposed around the rigid support and spaced apart from the balloon, and integrally formed with the rigid support, said foldable plastic screen being capable of being initially in a folded position, before inserting the balloon assembly into the stomach, and capable of being spread out after crossing the stomach wall, said screen being configured to lay over a stomach external wall and attach thereon to seal an area of the hole formed in the stomach to prevent gastric juices from leaking.

18. (Original) An intragastric balloon assembly according to claim 17, wherein the foldable plastic screen is made of silicon.

19. (Original) A surgical procedure to set the intragastric balloon of claim 1 to treat a patient suffering from obesity, comprising the steps of:

- applying asepsis and antisepsis measures;
- anesthetizing the patient under an anesthesiologist surveillance;
- placing the patient in a ventral decubitus position;
- performing an abdomen antisepsis;
- setting sterile fields to limit superior hemiabdomen;
- introducing a central view flexible endoscope through a mouth of the patient;
- identifying the stomach inflated with air by means of the endoscope;
- pressing the bottom of a gastric body against the major curvature with the endoscope, to identify a puncture site by locating light through the abdominal wall;
- applying local anesthesia with diluted xilocaine without epinephrine at a puncturing site;
- making a small incision with a 2 mm knife;
- introducing a puncturing trocar at the puncturing site, by piercing all layers of the abdominal wall and perforating the stomach, watching this operation through the endoscope ;
- removing a pointed mandrin from trocar ;
- introducing into the stomach a resistant suture through the light of trocar ;
- taking the suture with the pliers of an endoscope and taking away the endoscope together with the suture through the mouth;
- tying the suture to the handle of the rigid support;
- making traction of the suture through the abdominal wall so that rigid support along with the catheter and the balloon are carried throughout the digestive tube to the stomach, the rigid support and inflating catheter being taken through the gastric wall and the abdominal wall;
- removing the percutaneous trocar;

carrying out a surgical incision of 5-7 cm;
cutting the skin and cellular tissue up to the aponeurosis;
dissecting aponeurosis surface to place the fixing plate on this site;
separating the inflating catheter from the rigid support and cutting the a tip of the rigid support;
inflating the balloon with a fluid;
making traction of the rigid support for the balloon to be attached to the gastric wall and the gastric wall in turn to be adhered to abdominal wall at the peritoneal layer to avoid leakage of gastric content towards the abdominal wall;
fixing the rigid support and introducing it through the first hole , cutting excess of the rigid support and fixing it to the flange by a suture;
fixing the inflating catheter by passing it through a hole of fixing plate, close to the level of the plate flange; cutting the inflating catheter and connecting the inflating catheter to the inflating valve;
fixing the fixing plate to the anterior aponeurosis of the abdomen by suture through fixing holes ;
setting the inflating valve in adjoining way to the incision, perforating the cellular tissue at a distance of 5-6 cm from outside and fixing it to the aponeurosis with suture and;
closing the subcutaneous cellular tissue and the skin.

20. (Original) A surgical procedure according to claim 19 including the step of applying a layer of a material promoting fibrosis and cicatrisation over rigid support and the balloon on the regions having contact with the tissues, once they have been taken to the stomach of the patient.

21. (Original) A surgical procedure according to claim 19 including the steps of: spreading out the foldable screen once the area of rigid support bearing screen has crossed the stomach wall, so that said screen lays over the stomach external wall and is attached thereon sealing the area of the hole formed in the stomach to prevent gastric juices from leaking.

22. (Original) An intragastric balloon assembly for reducing the food intake of a person suffering from obesity, in the intragastric balloon assembly comprising:

a balloon made of an acid resistant distensible material;

an inflating catheter joinable at one end to the balloon and configured to inflate the balloon;

a rigid support included an elongated element formed unitarily with the balloon and having a diameter that is larger at an end joined to the balloon and becomes smaller towards an opposing end, said rigid support being configured for use as a guideline and tractor to take the balloon into a stomach through a mouth and as a support to maintain the balloon in a substantially fixed position, said rigid support having a handle disposed at the opposing end of the rigid support and formed unitarily with the rigid support to permit said rigid support to be held during surgery;

said inflating catheter being detachably joined to the balloon to permit the inflating catheter to be detached from the balloon after inflating;

an inflating valve disposed at a point distant from the rigid support, fixedly attached to the balloon, and connected with detachable catheter for an initial inflating of the balloon; and

a fixing plate having a first hole with a circular flange configured to adjust and fix the rigid support and a plurality of fixation holes to join plate to abdominal tissue.

23. (Original) An intragastric balloon assembly according to claim 22, wherein the capacity of the balloon is about 200 to 1000 c.c.

24. (Original) An intragastric balloon assembly according to claim 22, wherein the balloon has a substantially circular shape.

25. (Original) An intragastric balloon assembly according to claim 22, wherein the balloon has a substantially bilobated shape.

26. (Original) An intragastric balloon assembly according to claim 22, wherein the balloon has a substantially kidney shape.

27. (Original) An intragastric balloon assembly according to claim 22, wherein the rigid support is made of silicone.
28. (Original) An intragastric balloon assembly according to claim 22, wherein the inflating catheter has diameter of about 1.5 to 2.0 mm and a length of approximately 20 cm.
29. (Original) An intragastric balloon assembly according to claim 22, wherein the fixing plate has a thickness of approximately 1.5 mm, and is made of at least one of silicone and inert plastic of higher hardness.
30. (Original) An intragastric balloon assembly according to claim 22, wherein the fixing plate has a shape selected from circular, ovoid and squared.
31. (Original) An intragastric balloon assembly according to claim 22, wherein the inflating valve is disposed in a point diametrically opposed to the rigid support.
32. (Original) An intragastric balloon assembly according to claim 22, wherein the rigid support and the balloon are partially covered by a layer of a material configured to promote fibrosis and cicatrization in regions that will contact tissues.
33. (Original) An intragastric balloon assembly according to claim 32, wherein the fibrosis and cicatrization promoting material is selected from goretex and mersilene.
34. (Original) An intragastric balloon assembly according to claim 22, further comprising a circular reinforcement disposed adjacent to a base of the balloon where the rigid support emerges, integrally formed with the balloon and having a plurality of embossments formed thereon radially distributed on an edge thereof, said circular reinforcement being configured to be adhered to an inner wall of the stomach, when setting the balloon assembly in place, to seal a hole formed therein.
35. (Original) An intragastric balloon assembly according to claim 34, wherein the circular reinforcement is made of the same material as the balloon.

36. (Original) An intragastric balloon assembly according to claim 34, further comprising a foldable plastic screen, disposed around the rigid support and spaced apart from the balloon, and integrally formed with the rigid support, said foldable plastic screen being capable of being initially in a folded position, before inserting the balloon assembly into the stomach, and capable of being spread out after crossing the stomach wall, said screen being configured to lay over a stomach external wall and attach thereon to seal an area of the hole formed in the stomach to prevent gastric juices from leaking.

37. (Original) An intragastric balloon assembly according to claim 36, wherein the foldable plastic screen, is made of silicon.

38. (Original) A procedure to set the intragastric balloon of claim 22 to treat a patient suffering from obesity, comprising the steps of:

- applying asepsis and antisepsis measures;
- anesthetizing the patient under an anesthesiologist surveillance;
- placing the patient in a ventral decubitus position;
- performing an abdomen antisepsis;
- setting sterile fields to limit superior hemiabdomen;
- introducing a central view flexible endoscope through a mouth of the patient;
- identifying stomach of the patient inflated with air by means of the endoscope;
- pressing a bottom of a gastric body against a major curvature with the endoscope, to identify a puncture site by locating light through the abdominal wall;
- applying local anesthesia with diluted xilocaine without epinephrine at a puncturing site;
- making a small incision with a 2 mm knife;
- introducing a puncturing trocar at the puncturing site, by piercing all layers of the abdominal wall and perforating the stomach, watching this operation through the endoscope;
- removing a pointed mandrin from trocar;
- introducing into the stomach a resistant suture through the light of trocar;

taking the suture with the pliers of an endoscope taking away the endoscope together with the suture through the mouth;
tying the suture to the handle of the rigid support;
making traction of the suture through the abdominal wall so that the rigid support along with the balloon and catheter are carried throughout a digestive tube to the stomach, the rigid support being taken through the gastric wall and the abdominal wall;
inflating the balloon through detachable catheter that is partially exposed at that time through the patient's mouth to a partial volume of about 200 to 300cc that allows exerting tension between the rigid support and the inflated balloon, so as to close the perforated stomach wall to the parietal peritoneum layer;
separating the inflating catheter from the balloon;
removing percutaneous trocar;
carrying out a surgical incision of 5-7 cm;
cutting the skin and cellular tissue up to the aponeurosis;
dissecting aponeurosis surface to place the fixing plate on this site;
making traction on the rigid support for the balloon to be attached to the gastric wall and the gastric wall in turn to be adhered to abdominal wall at the peritoneal layer to avoid leakage of gastric content to the abdominal wall;
fixing the rigid support and introducing the rigid support through hole, cutting excess of the rigid support and fixing the rigid support to flange by a suture;
fixing the fixing plate to the anterior aponeurosis of the abdomen by suture through fixing holes ;
closing the subcutaneous cellular tissue and the skin.

39. (Original) A surgical procedure according to claim 38 including the step of applying a layer of a material promoting fibrosis and cicatrisation over the rigid support and the balloon on the regions having contact with the tissues, once they have been taken to the stomach of the patient.

40. (Original) A surgical procedure according to claim 38 taken in combination with the intragastric balloon assembly of claims 34 to 37, including the steps of: spreading out the foldable screen once the area of rigid support bearing screen has crossed the stomach wall so that said screen lays over the stomach external wall and is attached thereon sealing the area of the hole formed in the stomach to prevent gastric juices from leaking.

41. (New) An intragastric balloon assembly for reducing food intake of a person suffering from obesity, comprising:

a balloon;

a tubular member for attaching the balloon to a gastric wall of a stomach of a person, the tubular member including a first end affixed to the balloon and a second end affixed to a handle;

a catheter detachably connected to the balloon and configured to inflate the balloon;
and

an inflation valve connected to the catheter.

42. (New) The intragastric balloon assembly of claim 41, wherein the catheter is disposed adjacent the tubular member.

43. (New) The intragastric balloon assembly of claim 41, a first end of the catheter is joined to the balloon and a second end of the catheter is connected to the inflation valve.

44. (New) The intragastric balloon assembly of claim 41, wherein the second end of the tubular member is configured to be anchored against a portion of an abdominal wall of the person to thereby attach the balloon to the gastric wall of the stomach of the person.

45. (New) The intragastric balloon assembly of claim 44, wherein tubular member is configured to be anchored against the portion of the abdominal wall with a plate member.

46. (New) The intragastric balloon assembly of claim 41, wherein the inflating valve comprises a self-sealing valve disposed in a wall of the balloon.

47. (New) The intragastric balloon assembly of claim 46, wherein the catheter is connected to the balloon at the self-sealing valve.

48. (New) The intragastric balloon assembly of claim 41, wherein the catheter is connected to the balloon at a location diametrically opposite a location where the tubular member is affixed to the balloon.

49. (New) The intragastric balloon assembly of claim 41, wherein the inflation valve includes a central aperture through which the tubular member is received.

50. (New) A method of installing an intragastric balloon assembly in a stomach of a patient, comprising the steps of:

providing the intragastric balloon assembly including a tubular member having a first end affixed to a balloon and a second end affixed to a handle, a catheter detachably connected to the balloon, and an inflation valve connected to the catheter;

identifying the stomach using the endoscope introduced through a mouth of the patient;

identifying a puncture site on a portion of an exterior portion of an abdominal wall of the patient;

piercing all layers of the abdominal wall at the puncture site and perforating the stomach to thereby introduce a first end of a suture into the stomach;

grasping the first end of the suture with the endoscope and pulling the endoscope and the first end of the suture through the mouth of the patient;

attaching the first end of the suture to the handle of the intragastric balloon assembly;

pulling a second end of the suture so that the first end of the suture, the intragastric balloon assembly is pulled into the stomach, and the tubular member and the catheter are pulled through the gastric wall and the abdominal wall;

inflating the balloon with a fluid through the catheter; and

fixing the tubular member and the catheter to the abdominal wall with a fixing plate to thereby secure the balloon against the gastric wall of the stomach of the patient.

REMARKS

Applicant respectfully requests that the foregoing amendments be made prior to examination of the present application.

Claims 41-50 are being added. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1-50 are now pending in this application.

Action on the merits is eagerly awaited. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date 9/7/04

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5300
Facsimile: (202) 672-5399

By Joann K. Corey
Joann K. Corey
Attorney for Applicant
Registration No. 52,769